

# A comparison of sea-cucumber based gel to conventional hydrogels in wound healing

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
11/01/2018	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
16/02/2018	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
15/10/2018	Other	

## Plain English summary of protocol

### Background and study aims

Gamat (sea cucumber) has been widely used as a traditional medication/supplement for various ailments in South-east Asia, e.g. Malaysia, Indonesia, Thailand, Philippines and China. Gamat extracts contain many nutrients which may play a role in tissue repair, and they have been tested in rats and as a toothpaste in humans. However, to date, there have been no studies on human wounds. The aim of this study is to assess the effectiveness of Gamat gel in comparison with hydrogel in the treatment of skin graft donor sites.

### Who can participate?

Patients with partial thickness wounds created as an after effect of skin graft harvesting

### What does the study involve?

Both gels are applied to the patient simultaneously on the same wound divided into two areas. The duration of treatment is 10-14 days with follow up at day 21, then at 6 to 9 weeks. The effect is judged as which wound heals more on a specific day. Pain tolerance, itch tolerance, and scar quality are also assessed on both wound surfaces.

### What are the possible benefits and risks of participating?

The results could show whether Gamat gel heals human cutaneous wounds faster or better. The risks would be allergic reactions, but these have not been reported so far.

### Where is the study run from?

Hospital Universiti Sains Malaysia (Malaysia)

### When is the study starting and how long is it expected to run for?

August 2016 to September 2017

### Who is funding the study?

Universiti Kebangsaan Malaysia (Malaysia)

### Who is the main contact?

Dr Adzim Poh Yuen Wen

# Contact information

## Type(s)

Public

## Contact name

Dr Adzim Poh Yuen Wen

## ORCID ID

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## Contact details

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47500

# Additional identifiers

## Protocol serial number

USM/JEPeM/16060218

# Study information

## Scientific Title

A prospective case-control comparative study to evaluate the efficacy of Gamat gel in comparison with hydrogel in treatment of skin graft donor sites

## Study objectives

Null hypothesis: There is a no significant difference in the rate of epithelialization between Gamat gel dressing and Duoderm® Hydroactive® Gel dressing on skin graft donor sites.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Local ethics board in Hospital Universiti Sains Malaysia (JEPeM), 21/11/2016, ref: USM/JEPeM/16060218

## Study design

Single-center prospective single-blinded comparative study

## Primary study design

Interventional

## Study type(s)

Treatment

## **Health condition(s) or problem(s) studied**

Skin graft donor site wounds

## **Interventions**

This is a prospective, single-blinded, comparative clinical trial involving patients in Hospital Universiti Sains Malaysia with partial thickness wounds which were created as an after effect of skin graft harvesting. Any patient requiring skin grafting and fulfilling the inclusion/exclusion criteria will be approached preoperatively for recruitment. Both gels (sea-cucumber based gel and Duoderm (r) gel) will be applied on the patient simultaneously on the same wound, which is geometrically divided into two areas correspondingly. The effect is judged as which wound epithelializes more on a specific day. Pain tolerance, itch tolerance, and scar quality are also assessed on both wound surfaces. Duration of treatment 10-14 days. Follow up at day 21, then at 6 to 9 weeks.

## **Intervention Type**

Other

## **Primary outcome(s)**

Wound epithelialization, assessed by clinical judgment and calculated as percent of surface of wound epithelialized at day 10, 14 and 21 after intervention

## **Key secondary outcome(s)**

1. Pain and pruritus assessed with visual analogue scale at day 10, 14 and 21
2. Scar quality assessed with modified Vancouver scar scale (MVSS) at follow up (week 6 to 9)

## **Completion date**

04/09/2017

## **Eligibility**

### **Key inclusion criteria**

1. All patients with partial thickness wounds after split-skin graft harvesting
2. This thickness is at 0.2 mm (0.008 inch); harvested with a specified dermatome
3. Skin-graft donors > 25cm<sup>2</sup> wide
4. Consented patients
5. Patients compliant to the treatment protocol

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Mixed

### **Sex**

All

### **Key exclusion criteria**

1. Accidental full thickness harvesting
2. Non-compliant patient, causing dressing to dislodge
3. Patients with history of allergy to seafood/ sea cucumber
4. Patients with uncontrolled diabetes mellitus, on steroid medications or who are immunocompromised
5. Pregnancy
6. Patient with skin pathology (eczema etc)

**Date of first enrolment**

29/12/2016

**Date of final enrolment**

03/07/2017

## Locations

**Countries of recruitment**

Malaysia

**Study participating centre**

**Hospital Universiti Sains Malaysia**

Department of Reconstructive Sciences

Kubang Kerian, Kelantan

Malaysia

16150

## Sponsor information

**Organisation**

Hospital Universiti Sains Malaysia

**ROR**

<https://ror.org/0090j2029>

## Funder(s)

**Funder type**

University/education

**Funder Name**

Universiti Kebangsaan Malaysia

**Alternative Name(s)**

Universiti Kebangsaan Malaysia (UKM), Universiti Kebangsaan Malaysia (UKM), Malaysia, ukminsta, Universiti Kebangsaan Malaysia - UKM, Universiti Kebangsaan Malaysia (Malaysia), University Kebangsaan (Malaysia), UKM

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

Malaysia

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Adzim Poh Yuen Wen. A copy of the raw data has been submitted to the Medical Sciences Studies Centre (or Pusat Pengajian Sains Perubatan [PPSP]) of Hospital Universiti Sains Malaysia. All patients were assigned a coded number to protect anonymity.

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/12/2018		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes